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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,528	11/27/2001	Sheng-Ping Zhong	S13.12-0124	8767

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EXAMINER

SMITH, RUTH S

ART UNIT PAPER NUMBER

3737

8

DATE MAILED: 01/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/995,528

Applicant(s)

ZHONG ET AL.

Examiner

Ruth S Smith

Art Unit

3737

-- Th MAILING DATE of this communication appears on th cover sh et with the correspond nc address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-84 is/are pending in the application.
- 4a) Of the above claim(s) 29-55 and 71-84 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 and 56-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Election/Restrictions

Applicant's election of the invention of Group I in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 29-55, 71-84 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.

Specification

The disclosure is objected to because of the following informalities: On page 5, line 14, "field generator" should be inserted after "magnetic". On page 6, line 11, "ablation" is misspelled. Appropriate correction is required.

Claim Objections

Claims 7, 15, 59, 65 are objected to because of the following informalities: The term "polyethylene oxide" appears twice in the claims. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9, 14-16, 18-20, 24, 25, 56-57, 59, 63-65, 67, 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Young et al. Young et al disclose a medical device such as a catheter having paramagnetic particles incorporated there through in

order to provide enhanced detectability when viewed by magnetic resonance imaging. The paramagnetic particles are combined with suitable polymeric materials and extruded into a desired shape such as a flexible tube. The particles may be dispersed uniformly throughout the catheter or may be dispersed in a preselected pattern such as a circumferential band or an axial band extending partially or wholly along the length of the tube. The polymeric material may comprise materials such as Nylon, polyurethane, polyethylene, etc. The paramagnetic materials can comprise a paramagnetic cation incorporated or encapsulated together with a proton-donating fluid in a carrier particle. The paramagnetic ion may be any metal ion displaying paramagnetic properties, typically being an element of atomic numbers 21-29, 42, 44, and 58-70. Exemplary transition metal cations include Gd^{+3} , V^{+4} , V^{+3} , Cu^{+2} , Ni^{+2} , Cr^{+3} , Co^{+3} , Co^{+2} , Cr^{+3} , Fe^{+3} , Fe^{+2} , and the like. The cations will normally be in the form of a salt, including sulfates, chlorides, acetates, nitrates, and the like, as counter ions. With respect to claims 3, 6, 19, 25, see column 8, lines 16-38. Column 8, lines 40-59 discloses that the paramagnetic particles may be coated or encapsulated with a polymer to form a shell or film. The polymeric coatings disclosed are hydrophilic materials such as cellulose ethers.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8,10,11,17,21-23,26-28,60-62,66,68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al. Young et al disclose a medical device such as a catheter having paramagnetic particles incorporated there through in order to provide enhanced detectability when viewed by magnetic resonance imaging. The paramagnetic particles are combined with suitable polymeric materials and extruded into a desired shape such as a flexible tube. The particles may be dispersed uniformly throughout the catheter or may be dispersed in a preselected pattern such as a circumferential band or an axial band extending partially or wholly along the length of the tube. The polymeric material may comprise materials such as Nylon, polyurethane, polyethylene, etc. The paramagnetic materials can comprise a paramagnetic cation incorporated or encapsulated together with a proton-donating fluid in a carrier particle. The paramagnetic ion may be any metal ion displaying paramagnetic properties, typically being an element of atomic numbers 21-29, 42, 44, and 58-70. Exemplary transition metal cations include Gd^{+3} , V^{+4} , V^{+3} , Cu^{+2} , Ni^{+2} , Cr^{+3} , Co^{+3} , Co^{+2} , Cr^{+3} , Fe^{+3} , Fe^{+2} , and the like. The cations will normally be in the form of a salt, including sulfates, chlorides, acetates, nitrates, and the like, as counter ions. With respect to claims 3, 6, 19,25, see column 8, lines 16-38. Column 8, lines 40-59 discloses that the paramagnetic particles may be coated or encapsulated with a polymer to form a shell or film. The polymeric coatings disclosed are hydrophilic materials such as cellulose ethers. Young et al fails to specifically disclose where the different materials are deposited. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to dispose the extrusion material on either the inner lumen surface, the outer lumen surface or both because Applicant has not disclosed that such placement of the material provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with any

manner in which the material is disposed because both perform the same function of allowing the medical device to be visualized under MRI equally well.

Therefore, it would have been an obvious matter of design choice to modify Young et al to obtain the invention as specified in the claims. With respect to claim 17, the process of cross-linking material to enhance durability is old and well known and would have been obvious in that such is a well known expedient in the art.

Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al in view of Weber et al. Young et al disclose a medical device such as a catheter having paramagnetic particles incorporated there through in order to provide enhanced detectability when viewed by magnetic resonance imaging. The paramagnetic particles are combined with suitable polymeric materials and extruded into a desired shape such as a flexible tube. The particles may be dispersed uniformly throughout the catheter or may be dispersed in a preselected pattern such as a circumferential band or an axial band extending partially or wholly along the length of the tube. The polymeric material may comprise materials such as Nylon, polyurethane, polyethylene, etc. The paramagnetic materials can comprise a paramagnetic cation incorporated or encapsulated together with a proton-donating fluid in a carrier particle. The paramagnetic ion may be any metal ion displaying paramagnetic properties, typically being an element of atomic numbers 21-29, 42, 44, and 58-70. Exemplary transition metal cations include Gd^{+3} , V^{+4} , V^{+3} , Cu^{+2} , Ni^{+2} , Cr^{+3} , Co^{+3} , Co^{+2} , Cr^{+3} , Fe^{+3} , Fe^{+2} , and the like. The cations will normally be in the form of a salt, including sulfates, chlorides, acetates, nitrates, and the like, as counter ions. With respect to claims 3, 6, 19, 25, see column 8, lines 16-38. Column 8, lines 40-59 discloses that the paramagnetic particles may be coated or encapsulated with a polymer to form a shell or film. The polymeric coatings disclosed are hydrophilic materials such as cellulose ethers. Young et al fails to specifically disclose the use of dysprosium oxide. Weber et al disclose a catheter including paramagnetic materials to enable it to be visualized using MRI. The paramagnetic materials can comprise dysprosium oxide. It would have been obvious to

one skilled in the art to have modified Young et al such that the paramagnetic particles are dysprosium oxide. Such a modification merely involves the substitution of one well known type of paramagnetic particle for another.

Claims 12,13,70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al in view of Gillies et al. Young et al disclose a medical device such as a catheter having paramagnetic particles incorporated there through in order to provide enhanced detectability when viewed by magnetic resonance imaging. The paramagnetic particles are combined with suitable polymeric materials and extruded into a desired shape such as a flexible tube. The particles may be dispersed uniformly throughout the catheter or may be dispersed in a preselected pattern such as a circumferential band or an axial band extending partially or wholly along the length of the tube. The polymeric material may comprise materials such as Nylon, polyurethane, polyethylene, etc. The paramagnetic materials can comprise a paramagnetic cation incorporated or encapsulated together with a proton-donating fluid in a carrier particle. The paramagnetic ion may be any metal ion displaying paramagnetic properties, typically being an element of atomic numbers 21-29, 42, 44, and 58-70. Exemplary transition metal cations include Gd^{+3} , V^{+4} , V^{+3} , Cu^{+2} , Ni^{+2} , Cr^{+3} , Co^{+3} , Co^{+2} , Cr^{+3} , Fe^{+3} , Fe^{+2} , and the like. The cations will normally be in the form of a salt, including sulfates, chlorides, acetates, nitrates, and the like, as counter ions. With respect to claims 3, 6, 19,25, see column 8, lines 16-38. Column 8, lines 40-59 discloses that the paramagnetic particles may be coated or encapsulated with a polymer to form a shell or film. The polymeric coatings disclosed are hydrophilic materials such as cellulose ethers. Young et al fails to specifically disclose the use of an antenna in the device. Gillies et al disclose an MR visible catheter having an antenna mounted therein to provide enhanced MR imaging in the area to be diagnosed. It would have been obvious to one skilled in the art to have modified Young et al such that it includes an antenna for detecting MR signals. The advantage of such is to enable enhanced MR imaging in a specific area to be diagnosed in the patient as is well known in the art.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Rothbarth et al discloses coating a catheter with a hydrophilic material to improve the ease of inserting it into the patient.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S Smith whose telephone number is (703) 308-3063. The examiner can normally be reached on M-F 5:30 AM- 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dennis Ruhl can be reached on (703) 308-2262. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Ruth S Smith
Primary Examiner
Art Unit 3737

RSS